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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,321	DOEN ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/16/06, 7/18/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This application is a national stage application of PCT/JP04/18956, filed December 13, 2004, which claims priority to foreign application JP2003-419288, filed December 17, 2003. Claims 1-21 are pending in this application and examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to a composition, which is a single composition of matter containing certain definite components. However the claim limitations further specify that the components of the components of the composition are stored separately and then combined at the time of use. It is unclear from reading the limitation whether the composition that is the actual subject of the claim refers to the individual chemical compounds when stored separately or to the single composition resulting from mixing them in preparation for use. Therefore the claim limitations are indefinite.

Claim 21 provides for the use of an injectable composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what

method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections – 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 21 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* V. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 8-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doen et al. (PCT international publication WO02/15908, cited in PTO-1449, English translation filed as the specification of US patent 7396841 which is cited in

PTO-892) in view of Dietrich et al. (PCT international publication WO02/41919, reference included with PTO-1449)

Doen et al. discloses an aqueous injectable composition of a pharmaceutical composition having a sulfonyl-benzimidazole structure that includes lansoprazole. (column 2 lines 40-67, whereon A is unsubstituted, R1 id H, R_2 is CH_3, R_3 is OCH_2CF_3, R_4 is H) The composition additionally contains an alkali metal such as sodium hydroxide, (column 3 lines 47-50) N-methylglucamine, (column 3 lines 64-67) and a sugar alcohol such as mannitol. (column 4 lines 1-9) In one embodiment the composition contains 3.45 mg of sodium hydroxide, 10 mg or N-methylglucamine, and 60 mg of mannitol to 30 mg of the active compound. (column 4 lines 17-19) The composition can be freeze-dried or prepared as an injectable composition. (column 4 lines 22-48) The composition can be used in a method of treating digestive ulcer, gastritis, reflux esophagitis, non-ulcer-dyspepsia, gastric cancer, and ulcers caused by non-steroidal antiinflammatory drugs, hyperacidity, postoperative stress, or *Heliobacter pylori*. (column 4 line 66 – column 5 line 6) In a working example, 2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfiniy]-1H-benzimidazole is used as the active compound. (column 15 lines 61-65) Doen et al. does not disclose a composition containing EDTA.

Dietrich et al. discloses a freeze-dried composition of pantoprazole which is a benzimidazole proton pump inhibitor that has a very close structural similarity to lansoprazole, containing ethylendiamine tetraacetic acid or its sodium salt. (p. 2 paragraphs 3-4) The amount of EDTA is about 1-5% of the total pantoprazole, which

would come to about 0.3-6 mg of EDTA per 30 mg of active agent. (p. 3 paragraph 1) The composition can be prepared as a solution for injection. (p. 3 paragraph 2)

It would have been obvious to one of ordinary skill in the art at the time of the invention to make the compositions of Doen et al. with the addition of about 0.3-6 mg of EDTA per 30 mg of lansoprazole. One of ordinary skill in the art would have been motivated to add the EDTA because Dietrich et al. discloses that EDTA or sodium EDTA is useful for dissolving aqueous injectable solutions of a benzimidazole compound having a very similar structure to lansoprazole. One of ordinary skill in the art would have reasonably expected success because choosing appropriate pharmaceutical excipients is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doen et al. in view of Dietrich et al. as applied to claims 1-4 and 8-21 above, and further in view of Remington: the Science and Practice of Pharmacy. (Reference included with PTO-892, herein referred to as Remington)

The disclosure of Doen et al. in view of Dietrich et al. is discussed above. Doen et al. in view of Dietrich et al. does not disclose a composition filled in a plastic container or one wherein the components are separately stored.

Remington discloses plastic containers for packaging sterile preparations such as parental solutions. (p. 787, left column third paragraph) Plastics that can be used in

these containers include polyethylene, polyvinyl chloride, polyolefin, and silicone. (p. 787, table 41-1)

It would have been obvious to one of ordinary skill in the art at the time of the invention to store the compositions of Doen et al. in view of Dietrich et al. in plastic containers as described by Remington. One of ordinary skill in the art would have been motivated to use these containers because Remington already discloses them as being useful for storing parenteral compositions. One of ordinary skill in the art would have reasonably expected success because choosing a sterile container to store a pharmaceutical is well within the ordinary and routine level of skill in the art.

Furthermore with regard to the subject matter of instant claim 6, one of ordinary skill in the art would have recognized that individual components of a mixture can be stored separately and then combined. In fact any process of making a composition of the claimed invention will involve taking compounds which are stored separately and combining them at some point, thereby meeting the requirements of this claim.

Therefore the invention taken as a whole is *prima facie* obvious.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
10/6/2008

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623